CENTER FOR DRUG EVALUATION AND RESEARCH

Individual Safety Report

3357808-3-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

McNeil Consumer Healthcare
Ft. Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

Ufr/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	49 yrs or ____ Date of birth: [redacted]	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(x) death 2/17/97 (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): 2/17/97

4. Date of this report (mo/day/yr): 09/15/99

5. Describe event or problem

Notification by attorney's letter of DEATH allegedly associated w/ the use of a TYLENOL® acetaminophen product in an adult F client. Date of DEATH was listed as 2/17/97. Addl info rec'd 3/1/99: Summons & Complaint indicates decedent used Tylenol on an almost daily basis for headaches, backaches & all of uses indicated on the product label. It also indicates on or about 2/17/97, suddenly & w/o warning decedent died. An autopsy performed on 2/18/97 determined the cause of death as the result of acute LIVER NECROSIS caused by APAP toxicity.Addl info rec'd 9/13/99: Med records indicate pt was found by family after she collapsed on the floor unconscious (COMA). Approx 30 mins elapsed prior to arrival of EMS. Pt taken to ED intubated w/no pulses (HEART ARREST) or respiratory effort (APNEA). ED dx listed as CPA & DOA to ED. Death Certificate lists: acute liver necrosis, APAP toxicity, chronic ingestion of large amounts of APAP, hx of chronic headaches.Forensic pathologist report indicates pt's death due to acute cardiorespiratory failure (See Sect B7)

6. Relevant tests/laboratory data, including dates

2/18/97:no drugs by TLC,blood etoh level(-),APAP by HPLC: none at detection level of 0.5mcg/ml,autopsy micro (liver): marked acute vascular congestion in & around central veins, mild necrosis & moderate fatty change;est wt(autopsy)220-240

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1/7/91 hepatomegaly(sonogram),cholecystectomy(1/30/91),migraine headache,nervous bowel,back pain;occasional glass of wine w/dinner & special occasions (plaintiffs answer to interrogatory);NKDA (Sect B5 Cont) due to APAP toxicity.By hx, pt had been using large quantities of APAP daily. Although her drug screen showed no evidence of recent (See Sect C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Gelcaps

#2

2. Dose, frequency & route used

#1 8 gms over 2 days

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 2/11-2/12/97& over 3mo prior

#2

4. Diagnosis for use (indication)

#1 headaches, backaches

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown

#2

7. Exp. date (if known)

#1 unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

None.(Sect B7 cont) ingestion of APAP, her liver had damage consistent w/chronic APAP toxicity. Plaintiffs answer to interrogatory indicates decedent commonly ingested Tylenol products & ingested approx 16 gelcaps over 2 days(2/11-2/12)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

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2. Phone number: 215-273-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
(x) other: attorney

4. Date received by manufacturer (mo/day/yr): 09/13/99

5. (A) ~~NDA # 19-872~~
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 2

8. Adverse event term(s)

DEATH
COMA
APNEA
NECROSIS LIVER
HEART ARREST

9. Mfr. report number: 0930488A

E. Initial reporter

1. Name, address & phone #

[redacted] Esq.
[redacted] Avenue
[redacted]

SEP 27 1999

ADVERSE EVENT REPORTING SYSTEM

2. Health professional? ( ) Yes (X) No

3. Occupation: attorney

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.